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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,831	04/04/2002	Nathan W Levin	BET-105	5604

23520 7590 04/11/2007  
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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/089,831

Applicant(s)

LEVIN ET AL.

Examiner

Benjamin Huh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-28 and 30-40 is/are rejected.
- 7) ☒ Claim(s) 13 & 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/07 has been entered.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 & 21-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite an invention that produce a useful, concrete and tangible result, the claims only recite the calculation and determining of a volume. The examiner suggests the addition of a step for controlling the flow of dialysis fluid through the subject's peritoneal cavity using the calculated volume V.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 21-27, & 34-39 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

With respect to claims 1-11 & 21-27, the step of utilizing the data such as using to control the flow is omitted.

With respect to claims 34-39, the act of a practical use of the apparatus is omitted, since the claims state "and/or" controlling the flow it is possible not to control the flow and therefore can be non-statutory matter 101, it is suggested to amend the claims to state just "and" instead of "and/or".

With respect to claims 35-36 & 38-39, there is another omission which is the omission of actually determining the volume, the volume equation is essential to the claim, the claims only disclose the determining the subject-specific calibration constant K and utilizing the K value to control the flow. It is suggested that the applicant incorporate the equation for determining the volume V and it's respective formulas for the variables.

### ***Claim Objections***

Claim 12 is objected to because of the following informalities: Step B states "determining the volume of fluid in the peritoneal cavity while step (A) is being performed by a bioimpedance measurement directed at the peritoneal cavity" is seen to be read two ways, therefore for clarification purposes it is suggested to amend the claim

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to state "determining the volume of fluid in the peritoneal cavity by a bioimpedance measurement directed at the peritoneal cavity while step (A) is being performed".

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 14-20, 28, 30-33, & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peabody (US Patent No. 5643201) in view of Hagen (US Patent No. 4059169). The Peabody reference discloses a "Continuous Peritoneal Dialysis Apparatus" with a method of controlling a peritoneal dialysis procedure comprising continuously flowing dialysis fluid through a subject's peritoneal cavity; determining the volume of fluid in the peritoneal cavity, which is done by sensing or resistive sensing devices, and controlling the flow based on the volume determined, see col. 3 line 50 – col. 4 line 52; col. 5 lines 6-20 & 34-37; col. 8 lines 6-11, 49-67, & col. 10 line 8-24. Now even though Peabody does not explicitly disclose the use of bioimpedance measurement for determining fluid volume attention is directed to Hagen. The Hagen reference teaches the use of bioimpedance measurements to determine body fluids, see col. 2 lines 10-16. Therefore, it would have been obvious to one of ordinary skill in

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the art at the time of the invention to use the teachings of Hagen in the method of Peabody in order to accurately measure bodily fluids.

With respect to claims 17-20, where it would have been obvious to one of ordinary skill in at the time of the invention to select different times to achieve the desired treatment.

With respect to claim 40, wherein it would be obvious to one of ordinary skill in the art at the time of the invention to place the electrodes for the measurement at the location of the desired area to be measured in order to obtain a proper reading.

### ***Allowable Subject Matter***

Claims 13 & 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*BHH*

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*